SEP - 2 2005 K 051160

510(k) Summary
for
In Situ Systems Manipuseal

1. SPONSOR

Insitu Systems
26 Dakota Cres, Sockburn
Christchurch 8004
New Zealand
Contact Person: Paul Morrison
Telephone: 64-3-348-0203

Date Prepared: May 4, 2005

2. DEVICE NAME

Proprietary Name:	Manipuseal
Common/Usual Name:	Uterine Manipulator/Occluder
Classification Name:	Uterine Manipulator/Injector and Accessories

3. PREDICATE DEVICES

A & A Medical Uterine Manipulator	K010056
RUMI Koh Colpotomizer System Manipulator/Occluder	K954311

4. DEVICE DESCRIPTION

The Manipuseal device is comprised of an occluding balloon, Manipuseal uterine manipulator and tip, and a CO_2 Port. Manipulator consists of a toroidal or doughnut shaped balloon that is manufactured from silicone. The occluding balloon is designed to be inflated using a maximum of 180 ml of room air. The occluding balloon is an integral part of the Manipuseal device and is neither replaceable nor removable. The occluding balloon is filled using a commercially available 50 ml syringe. The occluding balloon occludes the vagina, while the Manipuseal manipulator is positioned in the patient and is used for manipulation.

The Manipuseal is a standard uterine manipulator, which consists of a handle, body and tip made from Acrylonitrate-Butadiene-Styrene (ABS). Once the manipulator tip is positioned in the cervix, the surgeon then commences the laparoscopic portion of the procedure. By moving the Manipuseal handle outside of the patient, the tip of the device moves, therefore positioning the cervix/uterus to provide a clearer view of the surgical field. The Manipuseal provides full anteversion, retroversion, and lateral motion for greater visibility and uterine movement

The CO_2 port is made up of a standard luer connection and is color coded green for easy identification. The insufflator is connected to the luer lock connector using a standard insufflator tube with an inline filter. The insufflator's maximum deliverable pressure is 14-16 mm Hg. It is also possible to produce pneumoperitoneum by connecting the insufflator to the trocar ports (a standard laparoscopic procedure).

5. INTENDED USE

The Manipuseal device is indicated for use in all laparoscopic surgical procedures where use of a uterine manipulator is appropriate and the surgeon intends to remove intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The overall design of the Manipuseal Manipulator/Occluder is similar to the design of the A & A Uterine Manipulator and the Koh Colpotomizer System. All of these devices consist of a uterine manipulator and an occluding balloon. The technological characteristics are similar in that the occluding balloons of both the proposed and predicate devices are filled with either water or room air in order to occlude the vagina. The only difference between the proposed and predicate devices is that the Manipuseal does not include a dye injector port, whereas the A & A device and the Koh Colpotomizer system offer a dye port. This minor difference does not affect safety or effectiveness since the main function of the proposed and predicate devices are the same in that they manipulate the uterus and provide an occluding balloon.

7. PERFORMANCE TESTING

Biocompatibility testing and Occluder Balloon burst testing was completed. This testing showed that the Manipuseal is biocompatible and the occluding balloon can withstand burst testing up to 2.5 times the recommended inflation.

A clinical study was performed in New Zealand which demonstrated that the Manipuseal was associated with less short term morbidity and a faster recovery rate during either abdominal or vaginal hysterectomy procedures in 358 patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2005

InSitu Systems
% Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K051160
Trade/Device Name: Manipuseal
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: HEW
Dated: August 15, 2005
Received: August 16, 2005

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K051160

Device Name: Manipuseal

Indications For Use:

The Manipuseal device is indicated for use in all laparoscopic surgical procedures where use of a uterine manipulator is appropriate and the surgeon intends to remove intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision.

Prescription Use _____X____ (Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyrm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051160